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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LANG, AMY T

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3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/753,848	Applicant(s) TRABADA ET AL.	
	Examiner AMY T. LANG	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-13, 22, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) 22 and 25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In the previous Non-Final action mailed 02/01/2008 ,claim 6 was erroneously indicated as allowable. Claim 6 includes similar limitations as claim 8 which was rejected. Therefore, the allowability of claim 6 is hereby withdrawn.

Claims 1-8, 10-13, 22, 24, and 25 are currently pending and claims 9, 14-21, and 23 are cancelled.

Specification

1. The disclosure is objected to because of the following informalities:
 - (i) line 2 of paragraph [0010] recites "make it is possible" which should be replaced with -- make it possible --.
 - (ii) line 2 of paragraph [0018] recites "a n electric motor" which should be replaced with -- an electric motor --.
- Appropriate correction is required.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 112. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the

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immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the anchoring module including an anchoring module drive mechanism for engaging the guide track to move the anchoring module along the guide track must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the lines, numbers, and letters are not uniformly thick and well defined (37CFR 1.84(i)) and they contain solid black shading which is not permitted (37CFR 1.84(m)). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

5. Claim 24 is objected to because of the following informalities: claim 24 recites "the sub-steps" in line 2. However, only one step is included in the claim so that Applicant is encouraged to amend to "the sub-step". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 6 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites first recites wherein the modular device comprises a drive mechanism for engaging the guide track (lines 5-7). Then, claim 6 further recites "a drive mechanism" in line 8 of the claim. Therefore, it appears as though two separate drive mechanisms are claimed. It is unclear if Applicant intends to claim two separate drive mechanisms or if the drive mechanism in line 8 is intended to further limit the drive mechanism of the modular device.

Claim 12 recites a second extendible member coupled to the "modular device". However, it is the examiner's position it is unclear if Applicant intends the second extendible member to actually be coupled to the modular device, as stated in claim 1, or to the anchoring module. The instant figures show the anchoring module comprising two extendible members while the modular device does not comprise one extendible member.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-5, 7, 10-12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter (EP 0,976,417 A1) in view of Cohen et al. (US 5,167,239) and Ackerman et al. (US 6,802,825 B2).

With regard to claim 1, Ritcher discloses a guidewire (2) which, when in an operative position, extends through a body lumen to a desired location and therefore overlaps the instantly claimed guide track ([0010]). Catheter (15) comprises a modular device disposed over and therefore coupled to the guidewire ([0018]). The catheter can be removed from the guidewire so that it is selectively coupled to the guidewire. Ritcher further teaches that the catheter comprises a drive mechanism (1) that engages the guidewire to move the catheter along the guidewire ([0019]). The drive mechanism "crawls" along the guidewire to move the catheter along the guidewire ([0016]; [0019]).

However, Ritcher does not specifically disclose the guidewire comprising an anchoring module. Cohen et al. (hereinafter Cohen) discloses a guidewire with a distal anchoring balloon (Figure 1). A balloon (14) located on the distal end of the balloon is inflated to anchor and secure the guidewire at the desired location within a patient's lumen (column 3, lines 29-36).

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However, Cohen does not specifically disclose the balloon as moveable on the guidewire. Ackerman et al. (hereinafter Ackerman) discloses a balloon that is also expanded to anchor and secure a catheter in place within a lumen ([column 4, lines 44-48). Sleeve (12) is slid distally to expand and displace the balloon. Specifically, the sleeve is slid forward and over the proximal end of the balloon. This causes the fluid within the balloon to be displaced forward, toward the distal end (column 5, lines 35-44). Displacing the fluid also causes the balloon, or at least a portion of the balloon, to be slid forward as well. For instance, when a partially expanded balloon is compressed, the balloon surface is redistributed along with the fluid inside the balloon. The balloon has been moved to the desired location where the balloon is expanded to the size of a patient's lumen. Since the sleeve causes the balloon to become displaced, the sleeve clearly overlaps the instantly claimed anchoring drive mechanism.

Ritcher does not specifically disclose an anchoring mechanism on the guidewire. Cohen discloses a guidewire that advantageously comprises an anchoring balloon to secure the guidewire during catheter procedures. Ackerman teaches that it is known in the art to utilize an outer sleeve/drive mechanism to displace the balloon for expansion. The outer sleeve/drive mechanism would move along the guidewire and therefore be engaged with the guidewire. Therefore, it would have been obvious at the time of the invention for the guidewire of Ritcher to comprise the anchoring balloon of Cohen that is moveably displaced as taught by Ackerman.

With regard to claim 2, the guide track (2) of Ritcher is specifically disclosed as a guidewire.

With regard to claim 3, as shown in Figures 1 and 2 of Ritcher, the guidewire comprises a substantially helical surface. Additionally, Cohen teaches that helically coiled wires are well known in the art (column 1, lines 19-23).

With regard to claim 4, the drive mechanism (1) of the catheter (15) is specifically disclosed as a motor ([0015]).

With regard to claim 5, Ritcher discloses the drive mechanism as a miniature oscillating motor, which an electric motor encompasses (see paragraph [0001] of Strobl (US 2004/0183383 A1)).

With regard to claim 7, Ritcher further discloses the catheter as comprising a guide track receiving lumen (18) ([0018]).

With regard to claims 10 and 11, the balloon of Cohen is the extendible member and component 26 of Cohen overlaps the inflation lumen.

With regard to claim 12, catheter (15) of Ritcher, the modular device, also comprises a balloon (19) located on the exterior of the device (Figure 7). The balloon is expanded to deploy the stent, but is also capable of anchoring the modular device within a patient's lumen ([0019]). Therefore, balloon (19) overlaps the instantly claimed second extendible member.

With regard to claim 13, it is the examiner's position that the balloon (19) on the exterior of the catheter intrinsically comprises an inflation lumen. This is well known in the art to expand a balloon.

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11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richter (EP 0,976,417 A1) in view of Cohen (US 5,167,239) and Ackerman (US 6,802,825 B2) as applied to claim 1 above, and further in view of Kindlein (US 7,229,401 B2) or Ziegler et al. (US 6,971,990 B2).

Ritcher in view of Cohen and Ackerman disclose a modular device, comprising a motor, moveably disposed on a guidewire. However, Ritcher does not specifically disclose the movement between the two components as activated by gears.

Kindlein, as shown in Figure 6, discloses a moveable needle advanced and retracted within a housing due to moveable and interacting wheels. Although not specifically shown, it would have been obvious for the wheels to comprise threaded gears for more accurate movement. Zielger et al. (hereinafter Ziegler) also shows movement between threaded gears to advance an object (Figures 1 and 5).

Additionally, Ritcher discloses an electric motor to move the catheter. Merely replacing the electric motor with a mechanical action simplifies the device and allows it to safely enter a patient. Since a drive mechanism utilizing gears to move an object along a track is well known in the art, as taught by Kindlein and Ziegler, it would have been obvious to one of ordinary skill in the art at the time of the invention for the drive mechanism of Ritcher to be simplified into a gear mechanism.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richter (EP 0,976,417 A1) view of Kindlein (US 7,229,401 B2) or Ziegler et al. (US 6,971,990 B2).

Ritcher, as discussed in paragraph 11 and incorporated here by reference, discloses a modular device driven by a drive mechanism over a guide track. The drive mechanism comprises a motor that engages the guide track to advance the modular device along the guide track.

Ritcher does not specifically disclose the drive mechanism as a threaded member that rotationally engages the guide track. Kindlein, as shown in Figure 6, discloses a moveable needle advanced and retracted within a housing due to moveable and interacting wheels. Although not specifically shown, it would have been obvious for the wheels to comprise threaded gears for more accurate movement. Zielger et al. (hereinafter Ziegler) also shows rotational movement between threaded gears to advance an object (Figures 1 and 5). Additionally, Ritcher discloses an electric motor to move the modular device. Merely replacing the electric motor with a mechanical action simplifies the device and allows it to safely enter a patient. Since a drive mechanism utilizing gears to move an object along a track is well known in the art, as taught by Kindlein and Ziegler, it would have been obvious to one of ordinary skill in the art at the time of the invention for the drive mechanism of Ritcher to be simplified into a threaded gear mechanism.

Allowable Subject Matter

13. Claims 22 and 25 are allowed. Claim 24 is also found allowable pending the claim objection above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

08/27/2008
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Examiner, Art Unit 3731

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